

Attorney's Docket No:cardiobeat-3 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re application of George McBride, et al Filed: 03/27/2000 Title: Internet Device Operation for Medical Testing Serial No.: 09/535,888

:Examiner:SHABANA QURESHI : Art Unit 2155

RECEIVED

DECLARATION UNDER 37 C.F.R. 1.131 By DONALD J. LENKSZUS

MAY 17 2004

Technology Center 2100

I, Donald J. Lenkszus hereby declare as follows:

1. I am a patent attorney registered to practice before the United States Patent and Trademark Office. My registration number is 28,096.

2. My address is Donald J. Lenkszus, P.C., P.O. Box 3064, Carefree, AZ 85377-3064.

3. I prepared and filed the above-identified patent application on behalf of Cardiobeat.com, a Nevada Corporation that is the owner of the invention disclosed in the above-identified application.

4. On or about December 23, 1999, I met with George McBride and Robert Royce to discuss patentability of inventions.

5. On or about January 3, 2000, I again met with George McBride and Robert Royce to discuss patenting the invention claimed in the above-identified application as well as related inventions arising out of the same system and to receive disclosure materials to begin the preparation of the above-identified patent application and related applications. During the month of January 2000, I began preparation of the above-identified patent application.

6. On or about January 27, 2000, I again met with George McBride and Robert Royce to obtain further disclosure information and to discuss a preliminary draft patent application prepared by me.

7. Throughout the months of February and March 2000, I provided a further draft patent application to George McBride and Robert Royce for their review and comment.

8. I prepared a draft patent application and met with George McBride and Robert Royce on March 9, 2000.

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attorney docket: CARDIOBEAT-3

INVENTOR: McBride et al TITLE: Internet Device Operation for Medical Testing

9. During the period subsequent to March 9, 2000 and prior to March 27, 2000 George McBride and Robert Royce reviewed the patent application and provided comments to me. I prepared the final patent application and filed the same with the United States Patent and Trademark Office on March 27, 2000.

10. At all times from the initial meeting with George McBride and Robert Royce I was diligent in the preparation and filing of the above-identified patent application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Donald J. Lenkszus

Date: May 11, 2004

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DECLARATION UNDER 37 C.F.R. 1.131 By GEORGE MCBRIDE

RECEIVED

MAY 17 2004

I, GEORGE MCBRIDE hereby declare as follows:

Technology Center 2100

1. My address is 4519 East Peakview, Cave Creek, AZ 85331

2. On or prior to July 9, 1999, Robert Royce and I conceived the invention that is the subject of the above-identified patent application. Evidence of this conception is an emailed executive summary of the project dated July 09, 1999, a redacted copy of which is attached hereto as Exhibit 1.

3. Subsequent to the conception of the invention Robert Royce and I were diligent in reducing the invention to practice as evidenced by a continuous development activity pertaining to the reduction to practice of the invention. Subsequent to July 9, 1999, a new corporate entity was formed, Cardiobeat.com, to develop and market the invention. I prepared several draft development plans for the invention, one version of which was sent by email to Robert Royce and Larry MacDonald and which is attached hereto as Exhibit 2.

4. During the time that I was preparing the development plan, I and/or Robert Royce consulted with contract engineering firms relative to having assistance in reducing various aspects of the invention to practice. One such communications was an email from Warren Williamson dated August 17, 1999 that was forwarded to me by Robert Royce proposing design approaches to implementations of the invention. A copy of the email is attached as Exhibit 3.

5. From at least as early as August 17, 2002, Robert Royce worked substantially continuously and diligently at reducing the invention to practice as an employee and owner of Cardiobeat.com, assignee of the subject invention.

6. At frequent times throughout the development activity of the invention, we consulted with Dr. James Buell, regarding medical applications and impedance cardiography, which is used in the illustrative embodiment of the invention. One email communication that I received from Dr. Buell is attached hereto as Exhibit 4 dated 9/18/1999.

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TITLE: Internet Device Operation for Medical Testing

7. At all times subsequent to the conception of the invention, both Robert Royce and I continued to work on the reduction to practice of the invention including development of software. A portion of a business plan that I authored is attached as Exhibit 5, dated October 1, 1999, and describes a software program that was developed as part of this ongoing activity.

8. Robert Royce provided a status report to me by email dated October 15, 1999, attached as Exhibit 6, that discusses the development of aspects of the invention and includes an attached flow chart. The flow chart indicates that a portion of the database activity that is part of the reduction to practice of the invention is "about $\frac{1}{2}$ done at this time". The database activity was performed prior to October 15, 2002.

9. Development activity continued without interruption subsequent to the status report of October 15, 1999. On December 22, 1999, a meeting was held to review the development status of the invention. A copy of the overview of that development status is attached as Exhibit 7.

10. From December 23, 1999 through March 27, 2000, I along with Robert Royce had several meetings with Donald J. Lenkszus to disclose our invention and the illustrative embodiment development with him so that he could prepare and file patent applications on the subject invention and related inventions.

11. Warren Williamson of W.L. Williamson & Associates provided engineering services throughout this stage of the development activities up to and beyond the filing date of the subject patent application. Mr. Williamson provided engineering service at our direction to provide an implementation of the invention.

12. All the attached documents are true copies of original documents.

13. Throughout the period from conception of the invention through the filing date of the above-identified patent application, Robert Royce and I continuously and diligently worked on reducing the invention to practice either through our direct personal efforts and/or through direction of others in implementing various aspects of the product embodying the invention.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

George McB2de

Date: MAY 11, 2004



Attorney's Docket No:cardiobeat-3 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of George McBride, et al Filed: 03/27/2000 Title: Internet Device Operation for Medical Testing Serial No.: 09/535,888

:Examiner: SHABANA QURESHI : Art Unit 2155

DECLARATION UNDER 37 C.F.R. 1.131 By ROBERT ROYCE MAY 17 2004

I, ROBERT ROYCE hereby declare as follows:

Technology Center 2100

1. My address is 2427 Huber, Mesa, AZ 85213

2. At least as early as July 9, 1999, George McBride and I conceived the invention that is the subject of the above-identified patent application. Evidence of this conception is an emailed executive summary of the project dated July 09, 1999, a redacted copy of which is attached as Exhibit 1.

3. Subsequent to the conception of the invention George McBride and I were diligent in reducing the invention to practice as evidenced by a continuous development activity pertaining to the reduction to practice of the invention up to and beyond the filing date of the above-identified patent application. At no time from the date of conception of the invention through the filing date of the above-identified application did the development activity cease.

4. Subsequent to July 9, 1999, a new corporate entity was formed, Cardiobeat.com, develop and market the invention. I reviewed and provided input to George Mc Bride in the preparation of a development plan for the invention, one version of which was sent by email to me by George McBride and which is attached hereto as Exhibit 2.

5. Subsequent to at least as early as July 9, 1999 I contacted engineering firms to contract with them to assist in reducing the invention to practice. As a result of this activity, proposed design approaches to implementing aspect of the invention was received by me from Warren Williamson in an email dated August 17, 1999. A copy of the email as forwarded to George McBride is attached as Exhibit 3.

6. Subsequent to at least as early as August 17, 2002 I worked substantially continuously and full time in reducing the concept to practice as an employee/owner of Cardiobeat.com

7. At frequent times throughout the development activity of the invention, George McBride and I consulted with Dr. James Buell, regarding medical applications and impedance

NVENTOR: McBride et al

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TITLE: Internet Device Operation for Medical Testing

cardiography which is used in the illustrative embodiment of the invention. One email communication that I received from Dr. Buell is attached hereto as Exhibit 4 dated 9/18/1999.

8. At all times subsequent to the conception of the invention, both George McBride and I continued to work on the reduction to practice of the invention including development of software. As part of my full time activities in reducing the concept to practice, I prepared a status report that I sent to George McBride by email dated October 15, 1999, attached as Exhibit 5, that discusses the development of aspects of the invention and includes an attached flow chart. The flow chart indicates that a portion of the database activity that is part of the reduction to practice of the invention is "about $\frac{1}{2}$ done at this time".

9. On December 22, 1999, a meeting was held to review the development status of the invention. A copy of the overview of that development status is attached as Exhibit 6. I participated in that meeting and reported on activities indicated in the attached overview.

10. From December 23, 1999 through March 27, 2000, I along with George McBride had several meetings with patent attorney Donald J. Lenkszus to disclose our invention and the illustrative embodiment development with him so that he could prepare and file patent applications on the subject invention and related inventions.

11. Warren Williamson of W.L. Williamson & Associates provided engineering services throughout this stage of the development activities. Mr. Williamson provided a quotation for engineering service in a letter to me dated January 7, 2000, attached as Exhibit 7, as a result of earlier conversations that I had with him relative to providing engineering services relative to implementation of the invention at the direction of myself and George McBride. The quotation was accepted and Mr. Williamson provided engineering services for this aspect of the project beginning in January 2000.

11. Mr. Williamson provided engineering services as indicated by a report on Timing of Test Waveforms dated 2/1/00 attached as Exhibit 8; a communication, attached as Exhibit 9, regarding communications protocol dated 2/21/00 as revision 1 to an original dated 2/9/00; a document titled "Cardiobeat data contents" dated 2/28/2000, attached as Exhibit 10; and an invoice for services dated March 6, 2000, attached as Exhibit 11.

12. All the attached documents are true copies of original documents.

13. Throughout the period from conception of the invention through the filing date of the above-identified patent application, George McBride and I continuously and diligently worked on reducing the invention to practice either through our direct personal efforts and/or through direction of others in implementing various aspects of the product embodying the invention. I worked substantially full-time on reducing the invention to practice from at least as early as August 17, 1999 through the date on which the above-identified patent application was filed.

May 11 04 11:02a	DUNHLU LENKSZUS	400-010-1061	
		480-835-6559	р.1
May 11 04 11:03a	Robert Royce		•

NVENTOR: McBride et al TITLE: Internet Device Operation for Medical T sting

I hereby declare that all statements made herein of my own knowledge are tru and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Robert Royce

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Date: OCTOBER 20, 2003

att mey docket: CARDIOBEAT-3

INVENTOR: McBride et al TITLE: Internet Device Operation for Medical Testing

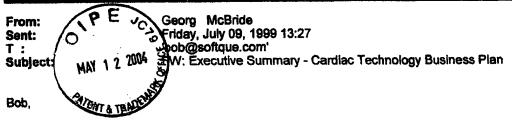
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EXHIBIT 1

GM Bride/cardi beat.com



The following Executive Summary was sent to Mike Buchanan for his comments. Larry and I would like your reaction and comments as a "fresh" reader. When you work on a document extensively the substance becomes familiar and objectivity is lost. Any comments to improve clarity would be appreciated.

The purpose of the summary is to sell the idea and convey the scope. Details (how this will happen) will be integrated into the business plan. We expect that you will be frustrated by the broad sweep of the summary. Even with that, will it sell the concept?

George McBride

Asset Technologies, Inc. Direct Phone: 602-418-0464 Office: 480-998-8900 Fax: 480-922-0500 Email: gmcbride@assettech.com Web Page: www.assettech.com

-----Original Message----

 From:
 George McBride

 Sent:
 July 09, 1999 13:18

 T :
 J. Michael Buchanan (E-mail)

 Cc:
 Larry Macdonald (E-mail)

 Subject:
 Executive Summary - Cardiac Technology Business Plan

Mike,

Please comment on this executive summary. Does it tell the story? Lets talk about how to proceed and how quickly we can move. The funding requirement is based on having a product available in 6 months with full deployment in a year.

Thanks again for the hospitality.

Draft Executive Summary.

CONFIDENTIAL, DO NOT COPY ...

DiagnosticDoctor.com

Executive Summary

About Cardiac Technology

Cardlac Technology (CT) has developed and is selling non-invasive diagnostic systems. The first product is Hemodynamic Monitoring (HD) a procedure that replaces invasive heart catheterization providing information on stroke volume, cardiac output, systemic resistance, and cardiac function indices.

The Portable Cardiac Lab (PCL), the current product, is sold to hospitals, private physicians, and emergency technicians to obtain patient cardiovascular information utilizing a noninvasive procedure at very low cost.

The proprietary software that performs HD is the most advanced analytical software of its kind.

Market Opp rtunity

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58 million Americans afflicted with heart disease spend \$259 billion each year on treatment. The international market is over twice the size of the US. Ever increasing medical care costs demand cost effective treatment programs like HD. The incidence of heart disease increases as life expectancy increases, such as, congestive heart failure and strokes. Hem dynamic parameters are critical in assessing cardiac function. Yet these parameters are currently difficulty and expensive to obtain. Currently the preferred method of obtaining this information is invasive catheterization, which is expensive and life threatening.

HD can be sold to the consumer through an internet implementation at a greatly reduced cost. The testing logic will be downloaded for each test. The data collection sensors can be connected into any PC with a serial port (or USB). HD software will be downloaded for each test on a fee basis. Test results will be stored in a database for use by physicians and thers. The cost of the sensors can be reduced to let the test on the consumer market. Pricing a single HD procedure at the versus statements and will expand the market to anyone in need.

HD will establish a channel for distribution of other tests and procedures, such as, stress and blood pressure tests. The FDA has approved HD for Cardio Dynamics, a competitor, along with Medicare reimbursement qualification. Cl[#] has not submitted an application for approval. Based on the Cardio Dynamics approval, CT expects that approval, when requested, will be forthcoming.

Testing over the Internet

As the cost of health care rises individuals are taking a greater role in their medical care for both preventive and remedial medicine. HD offers direct access to a key cardiovascular test for a small cost. Home testing is testing on demand for those with heart disease that require regular monitoring. Immediate access to key tests and equally rapid transfer of th results to the care group will become an essential part of quality treatment in the future.

Establishing this channel will provide for distributing other medical and health products. HD will be the first of many procedures sold over the Internet. Establishing this test will position the Cardiac Technology as a primary channel for medical care through the Internet.

Time to market

Rapid deployment is critical to dominating the market. The HD technology is state of art, tested, and complete. The Internet deployment capability must be completed for general deployment. CT plans to begin field-testing several hundred users in three months with larger tests in six months. Broad deployment would begin in 12 months.

Pricing and Revenue

The average cost per test is the fact of the 60 million Americans afflicted with heart disease used HD once each year, the revenues would be \$4.1 billion. CT expects HD will be used address a broad range of cardiac concerns from health interest to intensive care.

The channel developed for distributing HD can be used for advertising and distribution of related products and services.

Funding & Financial Summary

Need for Funding

CT is seeking Statement in funding to deliver the PCL Test through the Internet.

Funding is required to

- develop the Internet delivery system,
- upgrade the diagnostic code,
- construct the administrative and customer management systems,
- build the database to hold the test data, and
- reduce the cost of the sensors.

Pro Forma Financials

Cost have b	een forecast for t	he first year on	ly		•
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George McBride

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EXHIBIT 2

GMcBride/cardiobeat.com

From: Sent: T : Subject: George McBride Sunday, August 15, 1999 22:30 Bob Royce (E-mail); Larry Macdonald (E-mail) Two Pricings...

Gentleman,

The project plan has been adjusted to include additional resource for the Application development. The project plan $\frac{2}{3}$ should be frozen for plan generation.

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Larry.

The concentration should be on the strength plan.

But, if there is time, the reduced deferred Project Plan "Low Cost **gates**.." and a new column in the Infrastructure tab of the spread sheet can be used to generate a plan that comes in around **Statistics**. This would be a nice back up to the discussion if the question is asked, "Can you do it for less?". I have a meeting out of the office first thing, 0800 and will be in by 0900.

Th spreadsheet and 2 project plans are attached.

Low Cost - 1-3 1-3 Months Project First Cut Pro Months Project ... Plan.mpp (1... Forma.xls (116 K...

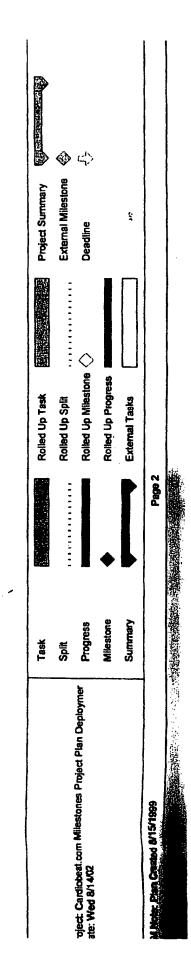
George McBride

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Asset Technologies, Inc. Direct Phone: 602-418-0464 Office: 480-998-8900 Fax: 480-922-0500 Email: gmcbride@assettech.com Web Page: www.assettech.com

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Start Up - Hiring, space, general Organization Work quickly to build work force try a competent force for Internet Deployment 2

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- Accounting System
 - utilize Profil
- set up prelimanary A/P - Get chart of accounts
 - Banking relations Payroll service
- Benefits Plan 6
- set up health insurance Stock Options (lawyers)
- Start recruiting Ģ
- Identify recruiting agencies to help locate candidates Set salary guidelines Start interviewing identify key technical resources that are required - Set plan for recruiting technical talent
- Deploy Prototype System (25 Patients) (Start+ 3 Months) Complete an end to end test ~
- Produce plan for getting to production quality by start + 6 months demonstrate download, test operation, upload utilize the best sensors that can be produced in 2 months Run tests on at least 20 patients
- internet Deployment æ

ATI possesses the infrastructure to begin work immediately Fast start will employ ATI facilities to perform these tasks.

- Acquire appropriate hardware and software Utilize the ATI Infrastructure to establish an operating environment Oracle / Application Server Cardiobeat.com web page Messaging Capability 0
- Configure a first generation server for performing the tast Set up with Oracle and utilize for Testing and Production This machine should be capable of handling at least 100,000 tests per month. Would include DASD to hold 5 million tests.
- Design and code Cardiobeat.com home web page Implement First Generation Web Servers Install all other development tools Create cardiobeat.com Web Page Install Oracle with OAS nstall Unix For the new box -2 -
- Evaluate and select ISP's m

Company Introduction Application for test patient Job opportunities

Find backup computing resorces for supporting high volumes that cannot be handled internally.

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	Emergency Procedures for out-of-line conditions		
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55 8	create inseructional video latinagement facility Video to instruct and demonstrate propar sensor attactment and	other procedures to the customer.	
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9 2	downfoed code over the web		
20	run the tests		
50 %	Observe / Change procedure Create Adminictronion ମାହ		
-	Start work on the Admin DB with resources that can be freed from the main effort.	the main effort.	
Ø I	Build (Admin) Patient set-up		
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	maintain tests purchased inventory		
	communicate account status to the customer monitor account status internally		
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. develop sales strategy based upon experience Create Instructional Video collaborate with the distribution group on the instructional video Investigate Cardiologist Review of Test Data Compile a coherent testimonial from individuals of stature in the Medical Profession. Alilances / product sharing Identify support facilities like video players • determine the requirements .' Part market research and part sales to the doctors -assess receptivity educate Introduce concept to selected MD's 3, identify suppliers negotiate and close • • **4**9 51 52 8

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// Note: Plan Created 8/15/1999

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EXHIBIT 3

GMcBride/cardiobeat.com

From: Sent: T : Subj ct: SoftQue [royce@softque.com] Monday, August 23, 1999 10:03 George McBride FW:

George I thought you might want to see this. rlr -----Orlginal Message-----From: Warren Williamson [mailto:warren@wlwill.com] Sent: Tuesday, August 17, 1999 1:45 PM To: royce@Softque.com Subject:

Bob:

3,

Following are my thoughts and observations about the next generation Thorasic Impedance Measurement System: The present Thorasic Impedance Measurement System design can be reduced greatly in size, cost, and power consumption by incorporating newer microprocessor technology which is now available. In particular. Digital Signal Processing (DSP) techniques can be used to perform the filtering and other signal processing functions which are implemented in the current design as individual amplifier and filter circuits. There are numerous DSP processors available now which are capable of performing these functions. In addition, performance will be improved with the use of these techniques. Much of the size and cost of the present design relates to the connectors, switches, display, and other interface components. There is plenty of opportunity for reduction in these areas. Another step which can be taken if necessary to futher reduce size is to use Surface Mount Technology. Even if not necessary for size reduction, it may be the best choice as this is a more modern assembly method and is becoming very widespread. The first step in the redesign process is to review the available microprocessor and DSP technology and select the appropriate processor based on cost, power consumption, external components required, and other design consideratons. We also need to carefully specify the product functionality with the features necessary for the way we intend to apply it. Then we can do the circuit and firmware design and produce circuit boards and prototypes. I'm looking forward to working with you again on this project. Warren

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attorney docket: CARDIOBEAT-3

INVENTOR: McBride et al TITLE: Internet Device Operation for Medical Testing

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EXHIBIT 4

Answers to questions regarding Impedance Cardiography

Acceptance:

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Impedance has not been widely accepted because its biophysics is not well investigated and the factors involved in the production of the signal are multiple and poorly understood. Impedance began to be promising about the same time that cardiac ultrasound came onto the scene. The physics of sonar was well researched; the technology proliferated rapidly and was marketed by many startup companies in the private sector. Virtually all of the research on impedance cardiography was done for the Apollo space flight by a team of researchers under Dr. William Kubicek, a physiologist at the University of Minnesota. The University held the patents on the device as the Minnesota Impedance Cardiograph. Like most universities, it was a disinterested entrepreneur, absent motivation from extensive clinical testing the technology languished. Computer power had to increase sufficiently to detect and assemble the average by separating the wandering "dirty" signal from cardiac impedance. Until the computing power was available, impedance would be seriously handicapped when comparing values against the "gold standard" for measuring cardiac output - measure the average of multiple cardiac cycles collected over a period of multiple seconds to minutes. Because it's accuracy was in question, and all of the gold standards for measuring cardiac output were invasive and thus not applicable to day to day monitoring any place but the intensive care unit, there was no precedent for it's use in the outpatient clinic setting. The medical community is conservative in embracing new ideas especially those not completely understood and explained by "hard " science facts and principles. Of course the electrocardiogram is still not completely explained and understood by hard science biophysics, but its utility has been accepted and validated through extensive clinical correlation and research, and even now new insights are gained annually about the electrocardiogram.

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Except for a few of us, there is little clinical experience with this technology and therefore the opportunity for, and participation in, experience with the technology must occur before widespread acceptance can follow.

This is where a research partnership with a few large hospitals could be helpful. To validate the technology requires correlation with invasive measurements and one large group that almost always gets monitored early post operatively are coronary bypass patients and heart surgery patients in general. Invasive monitoring lines are removed as early as possible to reduce the risk of infection, but if a noninvasive technique can be shown to be reasonably accurate, safe and cheaper than the invasive one, every hospital administrator in the country providing cardiac surgery and cardiac care services will want to pursue the more cost effective strategy. Considering the substantial costs of invasive monitoring and the affordable cost of impedance, the technique could be extended to cardiac rehabilitation and out patient heart failure monitoring and management. Congestive heart failure (CHF) is the most costly DRG for Medicare and is projected to expand almost exponentially in our aging population over the next 3 decades. The opportunity to substantially reduce the number of costly hospitalizations in the ever growing heart failure population and its economic impact on business government and society cannot be under estimated. I firmly believe that CHF is so much better treated with outpatient impedance directed therapy than with the typical inpatient course of care that only under extreme conditions such as sepsis or malignant arrhythmias should a patient with CHF be admitted to hospital. CHF is not a disease requiring hospitalization for it's optimum management. The disease must be managed in

the day to day environment where the patient lives. The strict diet, activity, and fluid restriction of the hospital environment only works until the patient leaves to go home, but is not applicable once he gets home, so he gets into trouble a little later and back he comes for another round of expensive care in the "ivory tower". Accurate, scheduled, hemo-dynamic surveillance can detect impending deterioration and direct appropriate treatment before the patient's condition reaches crisis proportions.

2) Demand and pricing:

The formula you used is right. If its' accuracy is valid then it's utility should be able to be proven. If it is perceived to have utility, widespread usage is inversely proportional to price.

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What we are considering is a new paradigm for "medical technology business" where the profit has traditionally been made from selling the machine or "hardware". The new model is service or software analogous in that the machinery is viewed as a linkage device decreasing in purchase price all the time while ISP's underwrite the hardware purchase to get consumers tied to long-term service agreements. Digital satellite dishes, cell phones, digital pagers, and essentially all new age machinery are useless without service providers. Hell, even your car has OBD so you can't tune it without special software in the hands of a select few service providers.

Jim Buell 9-18-99

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EXHIBIT 5

New Product BUSINESS PLAN FOR cardiobeat.com

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to deliver

"HEART TRACK"

an Internet based heart performance procedure for physicians and patients

17350 North Hartford Drive Scottsdale, AZ 85255 480-419-3956 email: plan@cardiobeat.com

Presented to:

10/1/1999

Copy _____ of _____ copies distributed

This business plan contains information that is not to be shared, copied, disclosed or otherwise compromised without the consent of cardiobeat.com.

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Executive Summary

Cardiobeat.com Plan

Cardiobeat.com (Cardiobeat) has developed a software product, "HEART TRACK", which will revolutionize heart health care and heart disease treatment throughout the world. The information collected dramatically improves cardiovascular health assessment. The relatively low price and "on demand" availability at homes, <u>physician's offices</u>, and hospitals will encourage increased usage. A database of tests taken periodically will support health management through trend analysis. The cumulative effect of regular testing, precise measurements, and computer analysis, will be improved cardiovascular health at greatly reduced costs.

Fifty eight million Americans suffer from heart disease and five million Americans are victims of heart failure. Heart disease is the most prolific killer and the most expensive area of medical treatment in America. Extrapolating the US statistics to the industrial world <u>populations</u>, <u>creates</u> projections of, 230 million victims of heart diseases and 21 <u>million victims</u> with heart failure. There is a large, motivated, prospect base.

"HEART TRACK" will be delivered over the Internet to patients and physicians. The user will purchase leads and sensors for performing the procedure. The "HEART TRACK" Software will be downloaded on demand for performance of the test with instructions. The user will plug the sensors into the serial port of the client workstation for data collection.

Cardiobeat is seeking \$1.5 million in initial capital to validate the commercial potential of "HEART TRACK" through productization of the software procedure and creation of the delivery capability. Deployment of "HEART TRACK" over the Web requires that Cardiobeat complete the following major tasks. These tasks are detailed in the attached project plan:

- 1. Productize the "HEART TRACK" software for use by novices
- 2. Build deployment management tools "HEART TRACK and a database to store "HEART TRACK" results
- Execute a sales and marketing plan to create demand for 25,000 tests per month in 7 months and protect the technology
- 4. Create a capital budget and execution plan for bringing "HEART TRACK" to a mass market product

The first phase of implementation is a three-month plan requiring 35 professionals to complete the tasks. Completion all components of the finished product will position Cardiobeat to begin the commercialization of "HEART TRACK" during the next three months of operation.

Today, lack of timely, precise, information inhibits management of cardiovascular health by patients and physicians. In many cases, the first symptom of heart disease is sudden death. "HEART TRACK" is a non-invasive procedure to augment and supplant the Right Heart Catheterization procedure, as the "gold standard" for diagnosing cardiovascular condition. "HEART TRACK" will be offered over the web for use in the physician's office or at home by the patient.

"HEART TRACK" is a sophisticated software tool for collecting, filtering, analyzing, and presenting detailed information about the cardiovascular system. Sensors, attached to the throat, and chest, of

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Executive Summery

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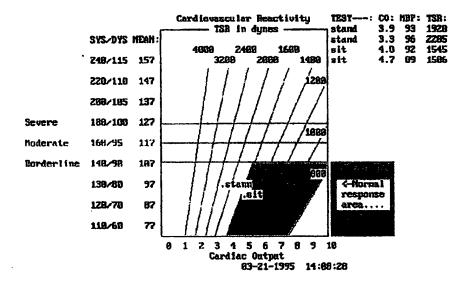
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the patient provide the facts necessary for performing the test. The sensors are connected to the Internet through a personal computer's serial port (or Universal Serial Bus).

"HEART TRACK" employs a medical technology called impedance cardiology. An undetectable alternating current is introduced into the body by placing circuit generating electrodes on the iorehead and distally on the abdomen. It is possible to measure resistance changes across the thorax. The drop in voltage between sensors is measured and mathematically reduced to produce a profile of the patient's cardio-vascular system, with results equivalent to an invasive heart cartherization.

The following graphic displays an easy to understand representation of three key measurements from the HEART TRACK test.



This chart illustrates the measurement of cardiovascular performance by plotting three variables and highlighting a normal area for a quick understanding of cardiovascular health. The upper right hand corner contains the raw plot data. The Graphic plots along each axis with a separate scale. "CO" is cardiac output in liters (the amount of blood pumped by the heart). "MBP" is the mean blood pressure, an averaging of the two measures (systolic and diastolic). "TSR" is Total Systemic Resistance to blood flow. TSR is a gauge of the resistance in the blood vessels to the flow of blood (clogged artery measurement). Summarization of this data into a single graphic provides a clear assessment of heart health. These variables are three of 19 measurements produced by HEART TRACK.

The measurements are taken 4 times over a 25-heartbeat test period per test. Two tests are sitting and two standing. The act of standing places a substantial strain on the heart. The hearts reaction to this strain is additional information relevant to heart health.

Executive Summery

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Periodic testing will provide trend analysis that will highlight changes in cardiovascular health. For example, the effect of exercise, weight change, and diet will be reflected in these measurements.

Impedance cardiology was invented in the 30's, employed in the 60's by NASA for the Apollo program, and offered commercially as a clinical instrument in the 80's by the predecessor company to Cardiobeat, Softque, Inc. Cardiobeat has purchased the technology from Softque, Inc.

The revenue potential is substantial, as "Heart Track will,

will generate substantial revenues. Fifty million tests per year at a price of \$50, a 10% penetration of the market, the revenues are \$2.5 billion. Additional capital will be required to reach this market share.

Mission Statement

To establish Cardiobeat with physicians, managed care organizations, hospitals, cardiovascular patients and key governmental advisory committees as the premier company at the center of the internet Health Care revolution

To establish HEART TRACK as the first significant economical and user friendly set of health care services from Cardiobeat that revolutionize the monitoring and treatment of heart disease in patients in the U.S. and worldwide

To manage the business of Cardiobeat in such a manner to maximize the ROI to its shareholders

To manage the business of Cardiobeat in a very professional and ethical manner so as to establish a reputation that will attract and retain customers and investors

To establish a follow up program that will enable Cardiobeat to market other non-invasive medical tests services to reinforce their commitment to heart disease and its related effects

"HEART TRACK" is a <u>Paradigm Shift in the</u> Management of Cardiovascular Health

The price and availability of "HEART TRACK" will change the way heart disease is managed.

Cardiobeat will deliver a product providing detailed heart health information at a dramatically lower price. Easy access to the test and its information will increase the patient's knowledge and encourage better compliance with treatment regimens. The amount of information for analytical purposes will increase to 100's of millions of data points. This information will create a new statistical base for understanding heart disease.

The record keeping function and its use for computing trends will become a magnet for other health information. Periodic testing amplified by trend analysis will encourage repeat visits. This partnership of health management through time will dispose patients to expand information content. Since the test collection and trend analysis will always be here, why not add medication history, and other medical information. Sharing with physicians is an added incentive.

Executive Summary

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3. Server software (Database & intelligent reports)

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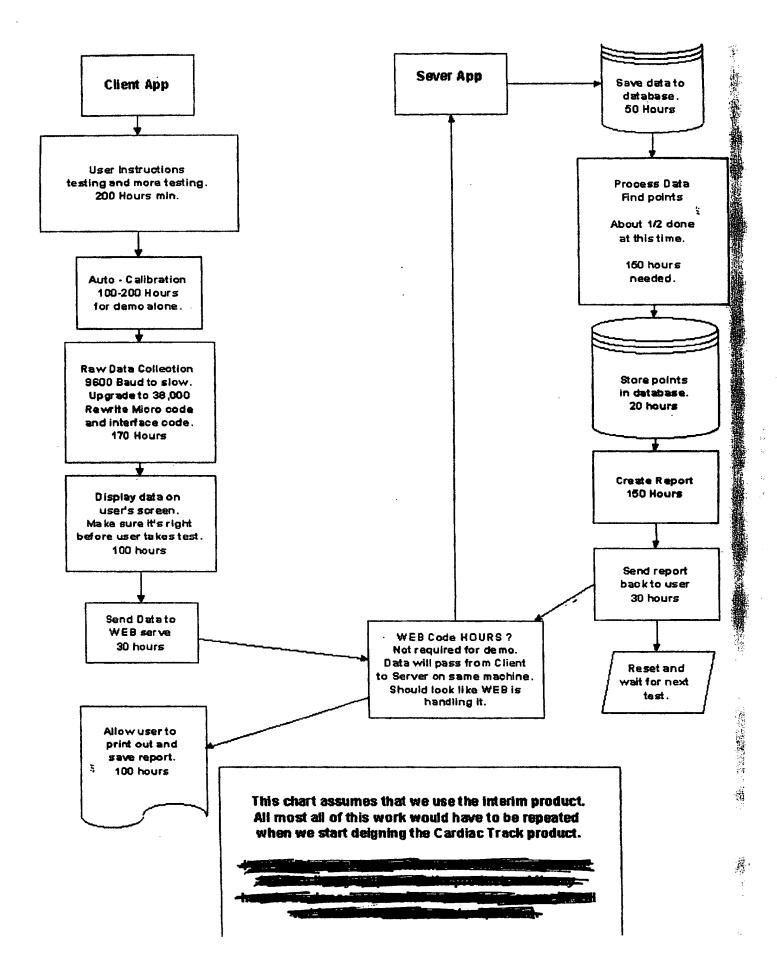
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attorney docket: CARDIOBEAT-3

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INVENTOR: McBride et al TITLE: Internet Device Operation for Medical Testing

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George McBride gmcbride@cardlobeat.com (480) 419-3957 17350 North Hartford Drive Scottsdale, AZ 86255

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December 22, 1999

Overview of software development status for the CARDIO-TRACK phase one product deliverable Server CARDIO-TRACK data reduction and analysis module code WEB data transfer application **Client application** User friendly tools Help AVI Videos (Sent with startup CD) Checks for misplaced sensors Checks for correct waveforms Click once to start test Press space bar or mouse to hait or suspend test Automatic Transmission from the host server to client Update Client application software (real time) Data movement Transmission to the host server from the client Data movement Server processing Processes data Create reports Routing to client & physicians E-Mail Reports Emergency calls Database Storage of Client data Communications between parties (patient and physician) Customer service module Patrick Smith - Data Base Administration The Oracle decision - what are the alternatives and why Oracle Scalability Web Interface capabilities Hardware Options Brett Scott – Microsoft Visual Basic / Web Coding The Microsoft environment Moving protected Data The User Interface **Bob Gubser – Sensor Manufacturing Describe PRA** Review Cardiobeat memo on sensor engineering and manufacturing Discuss early steps to produce prototype

Cardiobeat.com Sftwr Rev - Royce - 22Dec v2.doc

Page 1 of 2 8/15/02; 13:45



a paradigm shift in cardiovascular health

George McBride gmcbride@cardiobeat.com (480) 419-3957 17350 North Hartford Drive Scottsdale, AZ 86255

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Cardiobeat.com Software Status Review 22 December 1999 **Bob Royce** Overview of software environment CARDIO-TRACK test User friendly tools Help Videos Checks for misplaced sensors Transmission from the host server to client Application software Data movement Transmission to the host server from the client Data movement Routing to physicians Server processing Database Communications between parties (patient and physician) Customer service module CARDIO-TRACK test code Calculations Reporting Data transfers Patrick Smith – Data Base Administration The Oracle decision - what are the alternatives and why Oracle Scalability Web Interface capabilities Hardware Options Brett Scott - Microsoft / Web Coding The Microsoft environment Moving protected Data The User Interface **Bob Gubser - Sensor Manufacturing** Describe PRA Review Cardiobeat memo on sensor engineering and manufacturing Discuss early steps to produce prototype Characterize the prototype Items for the future Help Support "Use" Video's **Customer Support Modules** Volume test storage subsystem

Cardiobeat.com (Sftwr Rev - Pothier - 22Dec.doc)



George McBride <u>gmcbride@cardiobeat.com</u> (480) 419-3957 17350 North Hartford Drive Scottsdale, AZ 86255

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Characterize the prototype

Items for the future

Help Support "Use" Video's Customer Support Modules Volume test storage subsystem

Cardiobeat.com Sftwr Rev - Royce - 22Dec v2.doc

Page 2 of 2 8/15/02; 13:45



W. L. Williamson & Associates Consulting Engineers 528 S. Extension Rd. Mesa, Az. 85210 PH (480) 833-5202 FAX (480) 833-5529 www.wlwill.com

Robert L. Royce Vice President Cardiobeat.com

January 7, 2000

Re: Quotation # 000107-1

Bob:

Considering the very short time frame and limited resources available, I believe the following is the best approach for this step in the Impedance Measurement development:

1. Reduce the size and cost by eliminating functions not needed in the present concept. Keep the basic approach the same -- analog signal processing followed by the A/D and serial transmission to the PC.

2. Redesign the necessary portions to eliminate those problems which you have identified in the present prototypes.

3. Make other cost and size reduction changes where they can be identified as "low risk", i.e. those that we can be reasonably sure will not add a lot of delay to the program.

We should be able to produce something approximating the size of the enclosure which I showed you during our meeting Thursday. Although I can't cost everything out until the design is done, we should be able to build it in 100 pc. quantities for something in the neighborhood of \$50 -- \$75 each.

Early in the redesign phase we should also look at some other potential cost savings. For example, the filters we are currently using account for \$13 of material costs (100 pc. quantities). How much filtering do we really need? The requirement should be less if we have no connection to the power line system. Also, we can use a microcontroller with a built in A/D converter thereby cutting the cost of the two separate devices approximately in half. There are other potential savings that would not add much development time. If we can quickly evaluate the potential savings vs. risk, we should do so.

Following is my proposed development plan. There will necessarily be some overlap in the steps as proposed. This is a very aggressive development schedule. However, it is achievable. I am assuming I will not be responsible for any PC software development.

Because of the developmental nature of the project, I have quoted "not to exceed" costs. The actual costs may be somewhat less, but not more than the amounts below unless the scope of the development changes by mutual agreement. Engineering time is billed at 110/hr. Technician/PCB Layout time is billed at 60/hr. Materials and other expenses are billed at cost + 20%.

Phase 1.

Redesign of known problem areas. Evaluation of potential cost/size saving circuit redesign. Prototyping and test of new circuits.

Time -- 2 weeks

Maximum Cost -- \$ 11,500

Phase 2.

Finalize circuit design and schematic. Firmware redesign. Mechanical design.

Time -- 1 to 2 weeks Maximum Cost -- \$ 9,500

Phase 3.

PCB design and layout. Fabricate prototype PCB. Purchase components. Build and Test Prototype.

Time 2 weeks Maximum Cost \$ 5,600

Total

Time -- 5 to 6 weeks

Maximum Cost -- \$ 26,600

Terms - \$ 8,500 with order

\$ 8,500 at completion of Phase 1\$ 8,500 at completion of Phase 2Balance of Costs at Completion of Phase 3.

By

Warren L. Williamson

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Timing of T t Waveforms WLW – 2/1/00

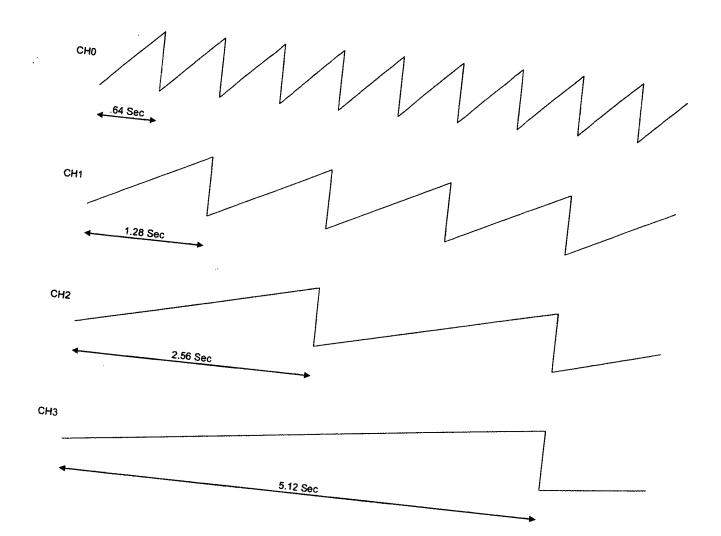
The Test waveforms consist of ramping waveforms (sawtooths) on all four channels. All four channels are continuously transmitted at 38.4 Kbaud in the format as described in "Cardiobeat Communications Protocol (Preliminary). Since 10 bits are transmitted for each byte (8 data bits + START + STOP), the maximum number of bytes per second which may be transmitted at this rate is 3840. We actually transmit 3200 bytes per second. Two bytes are transmitted for each channel and there are 4 channels so the sample rate is 400 samples/second/channel. (4 Channels x 2 bytes/channel x 400 samples/second)

The Channel 0 data is incremented once for every transmission (400 times per second). Therefore it makes a complete cycle of 256 steps in 256/400 seconds, or .64 seconds.

The Channel 1 data is incremented every other transmission (200 times per second). There are two transmissions of the same data. Therefore it makes a complete cycle of 256 steps in 256/200 or 1.28 seconds.

The Channel 2 data is incremented every fourth transmission (100 times per second). There are four transmissions of the same data. Therefore it makes a complete cycle of 256 steps in 256/100 or 2.56 seconds.

The Channel 3 data is incremented every eighth transmission (50 times per second). There are eight transmissions of the same data. Therefore it makes a complete cycle of 256 steps in 256/50 or 5.12 seconds.



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CARDIOBEAT COMMUNICATIONS PROTOCOL

PRELIMINARY

WLW - 2/9/00

REV1 - 2/21/00

Communication between the Impedance Measurement Unit and the Host is via a full duplex RS232 connection at 38.4 Kilobaud. Measurement data are sent to the Host as byte pairs, MSB followed by LSB. The MSN (Most Significant Nibble) of the 8 bit A/D data is sent as the lower four bits of the MSB. The LSN of the 8 bit A/D data is sent as the lower four bits of the LSB. Each byte pair conveys the following information:

- 1. The Byte ID (LSB or MSB) (b4 = 0 for LSB, b4=1 for MSB).
- 2. The A/D channel number (0-3) of the data contained in this pair (b7 and b6 of the MSB)
- 3. The A/D data MSN or LSN (b3 b0).
- 4. Calibrate/Normal mode. (LSB b6 = 1 in calibrate mode)
- 5. Note that b5 is always 1 in both MSB and LSB. This insures that no data byte will be an ASCII control character.

MSB Contents	b7	b6	b5	b4	b3,b2,b1,b0
	CH MSb	CH LSb	1	1	A/D MSN
LSB Contents	b7	b6	b5	b4	b3,b2,b1,b0
	spare	MODE	1	0	A/D LSN

The channel identification is as follows:

CH0 – ECG CH1 – dz/dt CH2 - DZ CH3 – Z0

Each channel is sampled and its data transmitted in turn so that 8 sequential bytes represent one sample of each of the 4 channels.

Using this protocol, up to 480 data points per second per channel may be transmitted at 38.4 Kbaud. (10 bits x 2 bytes x 4 channels x 480/sec). The actual data rate will be approximately 400 data points per second per channel.

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CARDIOBEAT DATA CONTENTS WLW – 2/28/2000

Each data sample may be represented as an 8 bit binary number with a value of 0 to 255 decimal. For the Z0 data (Channel 3) the data is unipolar with a scale of 50/255 Ohms per step. The value in Ohms may be obtained by multiplying the 8 bit unsigned value by .196.

The remaining 3 channels are referenced to approximately ½ scale (128 decimal). The actual reference value is the value obtained when the impedance device is in the CALIBRATE/NULL mode, hereinafter denoted NullValue. In operation, the real world value of the signal may be computed by subtracting NullValue from the signal value and multiplying by the appropriate scale factor. (Subtracting NullValue from the binary number puts the number in a 2s complement, 7 bit plus sign format)

The Scale factors are as follows:

CH0 – ECG: 27.8 microVolts/step. (3.56 mV full scale)

CH1 – dz/dt: -.0156 Ohm/sec./step (-2 Ohm/sec full scale)

CH2 - DZ: .00156 Ohm/step (.2 Ohms full scale)

CH3 – Z0: .196 Ohm/Step (50 Ohms full scale)

Examples:

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Assume the CALIBRATE/NULL mode produces a NullValue of 130 on CH0, CH1, and CH2. (In reality the three readings may be slightly different.)

Z0: 25 Ohms will produce a binary number of ~ 128. 128 x .196 = 25.088 (Ohms) (Var x .196) = ZO

DZ: -.1 Ohms will produce a binary number of ~ 66. (66 - 130) x .00156 = -.09984 (Ohms) (Var - Null) x .00156 = DeltaZ

dz/dt: -1 Ohm/sec will produce a binary number of 194. (194 – 130) x -.0156 = -.9984 (Ohms/sec)

 $(Var - Null) \times .0156 = dzdt$

 $(Var - Null) \times -.0156 = dzdt$ (Note negative sign on factor)

ECG: +1 mV peak will produce a binary number of 166. (166 - 130) x .0278 = 1.0008 (mV) (Var - Null) x .0278 = ECG

The way I read this I would compute as shown in blue. Right or Wrong. <u>rlroyce@yahoo.com</u>

CH0-ECG

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3.56 mV full scale. The ECG data is centered around half scale. That is, the output of the ECG amplifier is biased to 2.5 Volts with no signal present before being input to the A/D converter. With no signal, the binary data transmitted will be approximately 128 decimal (80 Hex). A positive signal on Lead 2 with respect to Lead 3 produces positive data.

CH1 - dz/dt

-2 Ohms/Sec Full Scale. The dz/dt data is centered around half scale. That is, the output of the dz/dt amplifier is biased to 2.5 Volts with no signal present before being input to the A/D converter. With no signal, the binary data transmitted will be approximately 128 decimal (80 Hex). The sense of the signal is inverted – a decreasing impedance produces a positive going signal.

CH2 – DZ

.2 Ohms full scale. The DZ data is centered around half scale. That is, the output of the DZ amplifier is biased to 2.5 Volts with no signal present before being input to the A/D converter. With no signal, the binary data transmitted will be approximately 128 decimal (80 Hex). An impedance greater than Z0 produces positive data (> 128). An impedance less than Z0 produces negative data (<128).

CH3 – Z0

50 Ohms full scale. The Z0 data is zero based. Zero Ohms produces a data value of zero. 25 ohms produces a data value of 128 (80 Hex). 50 Ohms produces a data value of 255. (FF Hex).

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Robert L. Royce Cardiobeat.com

March 6, 2000

Bob:

I am attaching our invoice # 4772 in the amount of \$8500. Per our agreement, the payment is due upon completion of Phase 2. Although the phases have become overlapped, we are certainly well along with Phase 3.

Following is an accounting of the actual expenditures to date:

Engineering - \$14,860.00 Technician - \$ 5,185.00 <u>Components - \$ 1,895.94</u> Total - \$ 21,940.94

The prototype is working well as far as I have been able to test. However, I have not yet checked with live signals. It will be very helpful to have the ability to display the real data. Do you have anything to give me yet?

We have most of the components to build several more prototype units. I estimate the labor to build and test them at \$500 each. This is outside the scope of our agreement and will represent additional charges. It may make sense to do a PCB re-layout before building more units. I will give you my recommendation on that after the prototype has been completely checked out.

I am very happy with the way the prototype is shaping up. It is much closer to the desired end product than originally envisioned by my proposal. I can now begin to put together some cost figures for 100's and 1000's of units.

Warren